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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,539	11/13/2003	Loran Paprocki	47563.0008	9183
57600	7590	11/28/2007		
HOLLAND & HART LLP P.O. Box 11583 60 E. South Temple, Suite 2000 Salt Lake City, UT 84110			EXAMINER EREZO, DARWIN P	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,539

Applicant(s)

PAPROCKI, LORAN

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-28 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18-28 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/4/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The applicant's amendment filed on 8/31/07 has been entered into the application.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/4/07 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-16, 18-28 and 38-43 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,662,681 to Nash et al.

(claim 1) Nash discloses a tissue puncture closure assembly (as seen in Figs. 1-4), comprising:

a closure device **106** having a distal and a proximal end (see Fig. 1);

a block and tackle (**36,110**) disposed in the closure device and anchored to the proximal end (block and tackle is being interpreted as a series of pulleys and cables; as seen in Fig. 1, portion **110** is resting against the proximal end of the closure device **106**);

a first filament **34** extending from portion **36** of the block and tackle;

an anchor **32** attached to the first filament at the distal end of the tissue puncture closure device;

a sealing plug **30** attached to the first filament between the anchor and the block and tackle; and

wherein the block and tackle (**36,110**) is capable of providing a mechanical advantage to move the sealing plug **30** and the anchor **32** together. As shown in Figs. 2-4, the anchor **32** and the sealing plug **30** are connected to the block and tackle **36** via filament **34** so that when the tamper member **106** is pushed down towards the block and tackle **36**, the block and tackle member **36** forces the anchor and the sealing plug to come together. Thus, the block and tackle provides a mechanical advantage to move the sealing plug and the anchor together.

a portion of the block and tackle **36** is moved by the tamper member **106** and

(claim 2) Portion **36** of the block and tackle is a plate having a plurality of holes disposed therein with a second filament **34D** anchored to the proximal end of the closure device and looping through at least two of the plurality of holes.

(claim 3) The second filament **34D** terminates with a pull-tab extending from the proximal end of the tissue puncture closure device (the top portion of the element **110**).

(claim 4) The plate comprises at least two holes extending therethrough, wherein the spacing between each holes at each end of plate is viewed as a riser. It is noted that the claim limitation does not clearly provide any structure for the term "riser".

(claim 5) The first filament is slidably attached to the anchor and the sealing plug.

(claim 6) The first filament extends distally from portion **36** of the block and tackle through the sealing plug and the anchor, back proximally toward the block and tackle, and is tied onto itself in a slip knot disposed between the block and tackle and the sealing plug.

(claim 7) The plurality of holes comprises three holes (see Fig. 2).

(claim 8) The first filament, the sealing plug, and the anchor are biologically resorbable (col. 8, lines 16-35).

5. (claims 9 and 10) See insertion sheath **102** having a fold in the distal end of the flexible tube (Fig. 1).

(claim 11) Nash discloses an internal incision sealing device comprising:

an internal component **32** configured to be positioned against an internal portion of an incision;

an external component **30** configured to be positioned at an external portion of the incision,

wherein the external component is attached to the internal component by a first slip-knotted filament **34B** such that tension on the first filament compresses the internal component and external component together; and

a block and tackle (**36,110**) disposed within the internal incision sealing device and operatively connected to the internal and external components (block and tackle is being interpreted as a series of pulleys and cables), wherein the block and tackle

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(36,110) is capable of providing a mechanical advantage to move the sealing plug 30 and the anchor 32 together. See the rejection to claim 1.

(claim 12) The block and tackle (36,110) creates a mechanical advantage such that the tension on a second filament traversing the block is multiplied and applied to the first filament, causing the slip knot to slide and compress the internal and external components together across the incision.

(claim 13) The internal incision is capable of being any type of incision, including an arteriotomy.

(claim 14) The second filament 34D is fixed to a cap of the sealing device at a first end, and free at a second end (see Fig. 2),

(claim 15) The second end further comprises a pull-tab (the top portion of element 110).

(claim 16) The block and tackle comprises at least two loops, creating at least a four to one mechanical advantage.

(claim 18) The internal component is an anchor shaped to advance in a low profile configuration through an insertion sheath, and automatically rotate into an expanded configuration upon exit from the insertion sheath and retraction of the sealing device.

(claim 19) The external component is a collagen sponge.

(claim 20) The internal component, the external component, and the first slip-knotted filament are biologically resorbable (col. 8, lines 16-35).

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(claim 21) The first slip-knotted filament is attached or looped through the block and tackle, and threads through the external component, through a hole in the internal component, and is knotted proximal of the external component.

(claim 22) Portion **36** of the block and tackle is a plate with at least two holes extending through.

(claim 23) The plate comprises at least two holes extending therethrough, wherein the spacing between each holes at each end of plate is viewed as a riser. It is noted that the claim limitation does not clearly provide any structure for the term "riser".

(claim 24) Nash discloses a sealing device, comprising:

an anchor **32** shaped to advance in a low profile configuration and automatically rotate into an expanded configuration when retracted;

a collagen sponge **30** connected in a loop to the anchor by a biologically resorbable filament; wherein tension on the biologically resorbable filament compresses the collagen sponge and the anchor together; and

a block and tackle **36** operatively connected to the biologically resorbable filament for generating a mechanical advantage (block and tackle is being interpreted as a series of pulleys and cables). See the rejection to claim 1 regarding the block and tackle providing a mechanical advantage.

(claim 25) The block and tackle is attached to a cap **110** of the sealing device via a second filament **34D**.

(claim 26) The second filament is fixably secured to the cap, loops between the block and the cap at least once, and extends out of the cap.

(claim 27) The block and tackle comprises a plate **36** with at least two holes extending through.

(claim 28) The plate comprises at least two holes extending therethrough, wherein the spacing between each holes at each end of plate is viewed as a riser. It is noted that the claim limitation does not clearly provide any structure for the term "riser".

(claim 38) Nash discloses a tissue puncture closure assembly (as seen in Figs. 1-4), comprising:

an anchor **32** and a sealing plug **30**; and

a block and tackle (**36,110**) coupled to the anchor and sealing plug via filament **34**, wherein the block and tackle (**36,110**) is capable of providing a mechanical advantage to move the sealing plug **30** and the anchor **32** together. See the rejection to claim 1 regarding the block and tackle providing a mechanical advantage.

(claim 39) Filament **34** extends multiple times between a proximal end and of the device and portion 36 of the block and tackle, which moves longitudinally.

(claim 40) The filament **34** can be pulled by a user via element 110 while the tamper member 106 is held to move the anchor and the sealing plug together.

(claim 41) Portion 36 of the block and tackle is a movable thick plate that causes the sealing plug and the anchor to move together.

(claim 42) The filaments are broken down to several filaments, including filament 34A, 34B, 34C and 34D.

(claim 43) The first filament, the sealing plug, and the anchor are biologically resorbable (col. 8, lines 16-35).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al.

Nash discloses the cap 110 being crimped onto the second filament 34D. Nash is silent with regards to securing the cap onto the filament via a stop plug. However, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to use any type of securing means, such as a stop plug or crimping, to secure the cap onto the filament because these means are well known in the art. Furthermore, the applicant has not provided any criticality for the cap being secured to the filament via a stop plug. Thus, either type of securing means would the same function of securing the cap onto the filament.

Response to Arguments

9. The applicant's arguments regarding the 35 USC 112, first paragraph rejection is persuasive and the rejection has been withdrawn.

10. The applicant's amendment to claim 14 has overcome the 35 USC 112, second paragraph rejection.

11. The applicant's arguments regarding the Nash reference are not persuasive.

The applicant's sole argument is directed toward Nash allegedly failing to disclose a block and tackle that provides a mechanical advantage. However, the applicant does not further clarify as to how Nash fails to provide this mechanical advantage.

Regardless, the rejection to claim 1 has been amended to show how the block and tackle of Nash is capable of providing a mechanical advantage to move the sealing plug and the anchor together.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Examiner
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